REMARKS

This Amendment is being submitted in response to the Office Action mailed on August 24, 2007 in connection with the above-identified application.

Reconsideration of the above-identified application in view of the following remarks is respectfully requested.

Status of Claims

Claims 1-7, 9-21 and 23-33 are currently pending and under consideration.

Claim Amendments

Claims 1 and 13 have been amended to recite that the patient is suffering from a "gastric disorder". No new matter has been added as a result of these amendments.

Claims 15-36 have been cancelled without prejudice. Applicant reserves the right to pursue these claims in one or more continuation application.

In view of these amendments, claims 1-7 and 9-14 are currently pending.

Rejection of Claims 1-7, 9-21, and 23-36 Under 35 U.S.C. §103(a)

The Office Action rejects claims 1-7, 9-21 and 23-36 under 35 U.S.C. §103(a) as being unpatentable over Phillips (U.S. Patent No. 6,489,346 B1) (hereinafter "Phillips I"). The Office further rejects claims 1-7, 9-21 and 23-36 under 35 U.S.C. §103(a) as being unpatentable over Phillips (U.S. Patent No. 5,840,737) (hereinafter "Phillips II") in view of Phillips I. Applicants respectfully traverse these rejections.

a) Rejection of Claims 1-7, 9-21 and 23-36 over Phillips I

The Examiner states that Phillips I teaches a method for treating acid-related gastrointestinal disorders comprising administering to a patient a non-enteric pharmaceutical composition comprising a non-enteric coated proton pump inhibitor in a pharmaceutically acceptable carrier and at least one buffering agent, wherein the pharmaceutically acceptable carrier comprises a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal (page 3 of Office Action). The Examiner further suggests that the Phillips I reference teaches that mixtures of the buffering agents can be used and such buffering agents include various bicarbonate and carbonate salts. More particularly, the Examiner states that the sodium bicarbonate range in Phillips I is in the amounts about 1000 mg to about 1680 mg, which overlaps in range with the range recited in claim 17.

As a preliminary matter, Applicants would like to point out that claims 15-36 have been deleted. As mentioned previously herein, claims 1-7 and 9-14 are currently pending.

Phillips I does not disclose or suggest a method of treating gastric acid disorders by administering to a patient suffering from a gastric acid disorder, a therapeutically effective amount of at least one non-enteric coated proton pump inhibitor in a pharmaceutically acceptable carrier, wherein the carrier comprises an equimolar ratio of sodium bicarbonate and sodium carbonate. Applicant believes that the present invention is distinguishable over Phillips I based on the unique buffering agent comprised of an equimolar ratio of bicarbonate salt and carbonate salt. Such equimolar ratio is not even contemplated nor obvious in view of Phillips I.

As discussed in Applicants' last Amendment, Phillips I does not either expressly or inherently teach the equimolar ratio of a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal. Similarly, Phillips I does not suggest or teach an equimolar ratio of sodium bicarbonate and sodium carbonate. Phillips I merely suggests that various combinations of salts may be used as a buffering agent, including bicarbonate salt and carbonate salt. Phillips I discloses a composition comprising a non-enteric coated proton pump inhibitor and at least one buffering agent. With respect to buffering agents, Phillips I states that the preferred buffering agent is sodium bicarbonate. (See, Phillips I, column 13, lines 33-40). Although the reference states broadly that "many other weak and strong bases (and mixtures thereof) can be utilized" and provides a non-exhaustive list of

examples of buffering agents including sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, etc., nowhere does Phillips I suggest an equimolar ratio of a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal. The non-exhaustive list of buffering agents provided in Phillips I does not even suggest the specific combination of sodium carbonate and sodium bicarbonate together, let alone provided specifically in an equimolar ratio. There simply is nothing in Phillips I that discloses or suggests to a skilled artisan to specifically select a combination of a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal in an equimolar ratio out of all the possible general buffer combinations disclosed in Phillips I.

While the Examiner admits that Phillips I does not "explicitly teach equimolar ratios of bicarbonate and sodium carbonate salts of Group IA metals" he says that differences in concentration will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating that such concentration is critical.

As Applicants have previously argued, it is known in the art that sodium bicarbonate produces gas while neutralizing stomach acids. The formation of this gas causes distension of the stomach which results in a bloated feeling, belching and flatulence. Also, it is also known in the art that sodium bicarbonate ingestion can cause the spontaneous rupture of the stomach (see Applicant's discussion or supporting art in Applicant's response filed August 29, 2006).

Throughout the specification, the superior results specifically attributable to the equimolar ratio of sodium carbonate and sodium bicarbonate (hereinafter referred to as "carbicarb") in treating gastric acid disorders are discussed and provided for, namely, the reduction in the comparative amounts of gas, including CO_2 gas, that is produced. As discussed on page 9, lines 5-11 of the specification, "gastric acid disorders are those disorders caused by imbalances between acid and pepsin production, called aggressive factors, and mucus, bicarbonate, and prostaglandin production, called defensive factors". The above mentioned reduction in gas reduces the distension of the stomach, belching and flatulence experienced by patients suffering from gastric disorders who take the compositions solely containing sodium bicarbonate (such as those compositions disclosed in Phillips I and Phillips II). In addition, patients suffering from gastric acid disorders ingesting

the compositions of the present invention may have a lower risk of stomach rupture when compared to patients suffering from gastric acid disorders who ingest compositions containing solely sodium bicarbonate.

As demonstrated by the Examples provided in the present invention, Applicants demonstrated that claimed equimolar ratio has an unexpected significant advantage over the prior art buffering agents. As discussed in the *Manual of Patent Examining Procedure*, Section 2144.05 III (8th Edition, Latest Revision August 2005), citing *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990):

> The last is replete with cases in which the difference between the claimed invention and the prior at is some range or other variable within the claims …[I]n such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.

Applicants therefore believe that they have demonstrated that the particular range (i.e., an equimolar ratio of bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal) is critical, since the use of this ratio results in a marked improvement relative to the prior art range. As discussed in the *Manual of Patent Examining Procedure*, Section 716.02 (8th Edition, Latest Revision August 2005), In *In re Waymouth*, 499 F.2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974), the court held that unexpected results for a claimed range as compared with the range disclosed in the prior art had been shown by a demonstration of "a marked improvement, over the results achieved under other ratios, as to be classified as a difference in kind, rather than one of degree." There simply is no teaching or suggestion anywhere in Phillips I that an equimolar ratio works better in treating patients suffering from gastric acid disorders than other possible buffer combinations. Furthermore, the kind of improvement includes the prevention of stomach rupture and other gas related maladies. It was, therefore, not obvious for a skilled artisan to arrive at the conclusion that the equimolar ratio is indeed important when treating patients suffering from gastric acid disorders. Accordingly, Applicants have satisfied the above discussed test.

b) Rejection over Phillips II in view of Phillips I.

The Examiner states that Philips II teaches a method for treating gastric acid disorders by administrating to a patient a single dose of a pharmaceutical composition including an aqueous solution/suspension of proton pump inhibitors in a pharmaceutically accessible carrier wherein the carrier comprises a bicarbonate salt of a Group IA metal. (See, Office Action, page 5). According to the Examiner, Phillips II also teaches a pharmaceutical composition which includes omeprazole or other substituted benzimidazoles and derivatives thereof in a pharmaceutically acceptable carrier wherein the carrier comprises a bicarbonate salt of a Group IA metal. The Examiner further states that Phillips II teaches a method for treating gastric acid disorders wherein the Group IA metal is sodium and potassium.

According to the Examiner, the pharmaceutically acceptable carrier taught by Phillips II includes the bicarbonate salt of the Group IA metal and can be prepared by mixing the bicarbonate salt of the Group IA metal, preferably, sodium bicarbonate, with water. The Examiner states that the concentration of the bicarbonate salt generally ranges from approximately 5.0% to about 60.0%. The preferred salt is sodium bicarbonate and its preferred concentration in the solution is about 8.4%. (See, Office Action, page 6).

The Examiner acknowledges that Phillips II does not teach a carbonate salt of a Group IA metal and thus does not explicitly teach the equimolar ratio of bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal. Similarly, Phillips II does not teach an equimolar ratio of sodium bicarbonate and sodium carbonate. Nevertheless, the Examiner raises the argument which is essentially identical to the Examiner's argument in the §103(a) rejection over Phillips I, namely, that while Phillips I does not "explicitly teach equimolar ratios of bicarbonate and sodium carbonate salts of Group IA metals" differences in concentration will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating that such concentration is critical. According to the Examiner, it is not inventive to discover the optimum or workable ranges by routine experimentation (citing *In re Aller*). The Examiner states that the prior art recognizes that need to administer lower amounts of bicarbonate to avoid adverse effects.

Applicants respectfully disagree. As discussed previously, Phillips I does not teach the equimolar ratio of a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal. While Phillips I disclosed a broad mixture of possible buffering agents,

there is no teaching or suggestion to use the equimolar mixture, specifically, carbicarb. Phillips II does not cure the deficiency of Phillips I since Phillips II does not teach a carbonate salt of the Group IA metal at all. On the contrary, Phillips II expressly states that in the preferred embodiment, omeprazole is mixed with a sodium bicarbonate solution to achieve a desired final omeprazole concentration. (See, Phillips II, column 7, lines 64-67). In fact, Phillips II is directed to a method of treating gastrointestinal conditions by administering omeprazole in a carrier with a bicarbonate salt of a Group IA metal, wherein the administration step consists of a single dosage. Therefore, a skilled artisan would not be motivated to replace the bicarbonate salt of a Group IA metal with an equimolar mixture of carbonate and bicarbonate. Moreover, as discussed above, Applicants believe that they have demonstrated that the particular range (i.e., an equimolar ratio of bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal) is critical, since the use of this ratio results in a marked improvement relative to the prior art range.

Therefore, Applicants respectfully submit that each of this rejections is improper and should be withdrawn.

CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Section 103. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 04-2223.

DykemaGossett PLLC
10 South Wacker Drive, Suite 2300
Chicago, Illinois 60606 USA
(312) 876-1700
(312) 627-2302 (facsimile)
www.dykema.com
ipmail@dykema.com

Respectfully submitted,

/ Lisa V. Mueller/
Attorney for Applicant
Reg. No. 38, 978

Date: January 29, 2008

Direct telephone calls to: 312-627-2184

CHICAGO\2328437.1
ID\LVM